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PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Nicolas C. Rivron; Paul V. Trescony; Michael F. Wolf Confirmation No. 8584  
Serial No.: 10/656,855  
Filed: September 4, 2003 Customer No.: 28863  
Examiner: Brian E. Pellegrino  
Group Art Unit: 3738  
Docket No.: 1023-271US02  
Title: IMPLANTABLE MEDICAL DEVICES HAVING RECESSES

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By:   
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**MAIL STOP APPEAL BRIEF - PATENTS**

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Alexandria, VA 22313-1450

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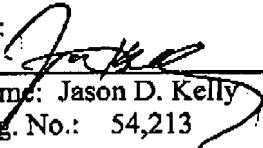
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By:   
Name: Patricia Cygan

**APPEAL BRIEF**

Mail Stop: Appeal Brief-Patents  
Commissioner for Patents  
Alexandria, VA 22313-1450

Sir:

This is an appeal from the Office Action mailed on December 22, 2006 finally rejecting claims 11, 12, and 14-41, and the Advisory Action mailed on March 12, 2007 affirming the rejection of claims 11, 12, 14-34 and 37-41. The Notice of Appeal was filed on March 22, 2007. The period of response for filing this Brief runs through May 22, 2007.

Please charge Deposit Account No. 50-1778 in the amount of \$500.00 to cover the required fee for filing this Brief. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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**REAL PARTY IN INTEREST**

The Real Party in Interest is Medtronic, Inc. of Minneapolis, Minnesota.

**RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences for the above-referenced patent application.

**STATUS OF CLAIMS**

Claims 11, 12, and 14-34, and 37-41 are pending and are the subject of this Appeal. The pending claims 11, 12, and 14-34, and 37-41 are set forth in Appendix A.

Claims 11, 12, 14-17, 19-22, 31-34, and 37-41 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 4,596,577 to Sato (hereinafter "Sato").

Claims 19, 23, 24-30, 33, and 34 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 6,352,555 to Dzau et al. (hereinafter "Dzau").

Claims 18 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sato.

**STATUS OF AMENDMENTS**

An Amendment in response to the final Office Action under 37 C.F.R. § 1.116 was filed on February 22, 2007. An Advisory Action, mailed March 12, 2007, indicated that the Amendment filed on February 22, 2007 was deemed not to place the application in condition for allowance, but would be entered for purposes of Appeal. The U.S. Patent & Trademark Office's Patent Application Information Retrieval (PAIR) system indicates the Amendment filed in response to the final Office Action was entered.

Applicant notes that the objection to the specification presented in the final Office Action is moot due to the entry of the Amendment filed in response to the final office Action. The objection was based on alleged failure of the specification to provide proper antecedent basis for "applying a frictional force to the luminal surface substantially in the absence of frozen liquid to lift nodes," as recited in independent claim 35 as previously presented. In the Amendment in

response to the final Office Action, independent claim 35 was canceled, thereby rendering the objection moot.

### SUMMARY OF CLAIMED SUBJECT MATTER

In general, the subject matter of pending claims 11, 12, 14-34, and 37-41 is directed to methods for preparing a surface of an implantable medical device.

Independent claim 11 is directed to a method comprising rubbing a luminal surface of a vascular prosthesis with a tool<sup>1</sup> to lift nodes from the luminal surface to define a plurality of recesses.

Independent claim 19 is directed to a method comprising applying a frictional force<sup>2</sup> to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluoroethylene (ePTFE), to lift nodes from the surface to define a plurality of recesses.

Independent claim 25 is directed to a method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface comprising nodes formed of polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses. In accordance with claim 25, the method further includes seeding cells on the surface.<sup>3</sup>

Independent claim 33 is directed to a method for treating a luminal surface of a vascular prosthesis that comprises ePTFE, the luminal surface comprising nodes and fibrils. The method of claim 33 comprises applying a frictional force to the luminal surface to lift at least some of the nodes from the luminal surface and form recesses. The lifted nodes are substantially free of attached fibrils.<sup>4</sup>

<sup>1</sup> See, e.g., Applicant's disclosure at FIG. 2; See also *id.* at page 6, lines 5-11 and page 12, lines 19-24.

<sup>2</sup> See, e.g., *id.* at page 10, lines 6-8 and page 12, lines 19-24.

<sup>3</sup> See, e.g., *id.* at page 13, lines 15-20.

<sup>4</sup> See, e.g., *id.* at page 7, lines 13-19 and page 8, lines 23-26.

Independent claim 37 is directed to a method for treating a luminal surface of a vascular prosthesis that comprises ePTFE, where the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and where the vascular prosthesis has a generally tube-shaped structure having an axis.<sup>5</sup> The method of claim 37 comprises rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses.

### GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The Appellant submits the following grounds of rejection to be reviewed on Appeal:

1. The rejection of claims 11, 12, 14-17, 19-22, 31-34, and 37-41 under 35 U.S.C. § 102(b) as being unpatentable over Sato;
2. The rejection of claims 19, 23, 24-30, 33, and 34 under 35 U.S.C. § 102(b) as being unpatentable over Dzau; and
3. The rejection of claims 18 and 38 under 35 U.S.C. § 103(a) as being unpatentable in view of Sato.

### ARGUMENT

The applied references, Sato and Dzau, fail to disclose each and every feature of the Appellant's claimed invention, as required by 35 U.S.C. § 102(b), and provide no teaching that would have suggested the invention of Appellant's claims or the desirability of modification to include such features, as required by 35 U.S.C. § 103(a). The Examiner has misinterpreted the scope and content of both Sato and Dzau, and reversal of the rejection of claims 11, 12, 14-34, and 37-41 is respectfully requested.

#### Rejection Under 35 U.S.C. § 102(b) in view of Sato

In the final Office Action, the Examiner rejected claims 11, 12, 14-17, 19-22, 31-34, and 37-41 under 35 U.S.C. § 102(b) as being anticipated by Sato. Appellant respectfully submits that the rejection of claims 11, 12, 14-17, 19-22, 31-34, and 37-41 is in error and should be reversed. In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a

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<sup>5</sup> See, e.g., *id.* at FIG. 1 and page 4, line 28 to page 5, line 4.

prior art reference must disclose each and every element of a claim.<sup>6</sup> If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper.<sup>7</sup> Sato fails to disclose each and every element of Appellant's independent claims 11, 19, 33, and 37, and accordingly, the Examiner's rejection of Appellant's independent claims was improper and should be reversed.

### Independent Claim 11

Independent claim 11 recites a method comprising rubbing a luminal surface of a vascular prosthesis with a tool to lift nodes from the luminal surface to define a plurality of recesses. Sato does not disclose each and every element of claim 11. For example, Sato does not teach or suggest lifting nodes from the luminal surface. Instead, Sato teaches rubbing techniques that result in a raised "nap . . . formed by fibrils from the original film, and partly torn material...."<sup>8</sup> Raising fibrils and partially torn material is not the same as raising nodes. Thus, Sato clearly fails to explicitly teach the requirements of independent claim 11.

In the final Office Action, the Examiner acknowledged the failure of Sato to explicitly teach the requirements of claim 11, and therefore argued that lifting nodes above a luminal surface is inherent in the nap-formation techniques taught by Sato. More particularly, the Examiner argued that, because it is known that PTFE includes interconnected nodes and fibrils, "it must be inherent [that] the fibrils lift the nodes with them [when the fibrils are raised according to the Sato nap-forming process] since they are connected."<sup>9</sup> Appellant respectfully disagrees with the Examiner's analysis of Sato.

The Examiner has failed to provide evidence or reasoning to suggest that nodes being lifted with fibrils is the only, or even the most likely, result of lifting fibrils according to the Sato method.<sup>10</sup> Other possible results of lifting fibrils according to the Sato method include stretching fibrils or breaking fibrils without lifting the nodes to any degree. In fact, the teaching in Sato of

<sup>6</sup> See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

<sup>7</sup> *Id.* See also *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ.2d 1766 (Fed. Cir. 1987); *In re Bond*, 910 F.2d 831, 15 USPQ.2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ.2d 1225 (Fed. Cir. 1998); *Oney v. Railiff*, 182 F.3d 893, 51 USPQ.2d 1697 (Fed. Cir. 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ.2d 1057 (Fed. Cir. 2000).

<sup>8</sup> Sato at column 4, lines. 12-14.

<sup>9</sup> Final Office Action mailed December 22, 2006, page 5, lines 3-5.

<sup>10</sup> See MPEP 2112 (the Examiner is required to provide evidence or a rationale tending to show inherency).



a "nap . . . formed by fibrils from the original film, and partly torn material"<sup>11</sup> appears to be most consistent with stretched and/or torn fibrils.

The Court of Appeals for the Federal Circuit has held that a finding of inherency is improper when the allegedly inherent teaching is merely one of a number of possibilities. For example, the Court has held:

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by mere probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."<sup>12</sup>

This authority is directly on point with the present case. Incidental lifting of nodes while lifting fibrils to create a nap according to the Sato method is, at best, a mere possibility. There is no evidence or rationale to support an assertion that incidental lifting of nodes while lifting fibrils to create a nap according to the Sato method in fact occurs. There is no hint or clue in Sato, or elsewhere in the evidentiary record, as to what happens to nodes when fibrils are lifted according to the Sato method. There is nothing but unsupported speculation, which cannot support a finding of inherency. Therefore, it is legally impermissible for the Examiner to argue that lifting nodes from the luminal surface to define a plurality of recesses, as required by independent claim 11, is inherently present in Sato.

For at least these reasons, the rejection of claim 11, and claims 12 and 14-17, which depend from claim 11, must be reversed.

### **Independent Claims 19 and 33**

Similar to independent claim 11 discussed above, independent claim 19 recites a method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including ePTFE, to lift nodes from the surface to define a plurality of recesses. Independent claim 33 recites a method for treating a luminal surface of a vascular prosthesis that comprises ePTFE, the luminal surface comprising nodes and fibrils, the method comprising applying a frictional force to the luminal

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<sup>11</sup> Sato at column 4, lines 12-14.

<sup>12</sup> *In re Robertson*, 169 F.3d 743, 745, 49 USPQ.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

surface to lift at least some of the nodes from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils.

The Examiner rejected independent claims 19 and 33 under 35 U.S.C. § 102(b) as being anticipated by Sato. For the reasons discussed above with respect to claim 11, Sato fails to disclose or suggest the requirements of independent claim 19. For example, for the reasons discussed above, Sato fails to apply a frictional force to medical device, as recited by claim 19, or a luminal surface of a vascular prosthesis, as recited by claim 33, to lift nodes from the luminal surface and form recesses. Sato fails to disclose this requirement, either expressly or inherently. As previously described, the Examiner has impermissibly relied on inherency, in an attempt to overcome a lack of disclosure in Sato that nodes are lifted with fibrils in the Sato method. The reliance on inherency is impermissible, because there is nothing that indicates that the missing descriptive matter in Sato is *necessarily* present, as alleged by the Examiner.

Independent claim 33 further recites "wherein the lifted nodes are substantially free of attached fibrils." Sato fails to disclose or suggest this further limitation of independent claim 33. Furthermore, the final Office Action did not address this further limitation of claim 33, which suggests that the Examiner did not consider it.

For at least these reasons, the rejections of claims 19 and 33 and/or the finality of the Office Action should be withdrawn.

#### **Independent Claim 37**

Independent claim 37 recites a method for treating a luminal surface of a vascular prosthesis that comprises ePTFE, wherein the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and wherein the vascular prosthesis has a generally tube-shaped structure having an axis, the method comprising rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses. Thus, similar to the independent claims discussed above, independent claim 37 requires rubbing a luminal surface to lift nodes from the luminal surface and form recesses. The Examiner rejected claim 37 under section 102(b) as being anticipated by Sato. For the reasons discussed above, Sato fails to disclose this requirement, either expressly or inherently.

Independent claim 37 further requires that the rubbing be in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface. As stated in Appellant's previous response, Sato does not even mention the orientation of fibrils, and is completely silent regarding a direction for the described brushing. Thus, Sato does not even remotely suggest rubbing in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface, as required by independent claim 37.

Nonetheless, the Examiner rejected claim 37 in the final Office Action. In support of the rejection of claim 37, the Examiner argued that "substantially parallel" is "terminology of relative degree, which has no basis of comparison," and therefore "considered broad and relatively unlimited in how it can be interpreted."<sup>13</sup> In other words, the Examiner argued that it does not matter that Sato fails to disclose or suggest rubbing in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface, because the term substantially parallel can be interpreted as broadly as needed to find anticipation. In this case, because Sato does not disclose any direction for brushing, the Examiner apparently construed the requirement in claim 37 of rubbing in a direction that is substantially parallel to both the axis of the vascular prosthesis and oriented fibrils of the luminal surface so broadly as to effectively read it out of the claim entirely.

This claim construction and finding of anticipation is reversible error. Appellant can find no authority that supports the Examiner's argument that that "substantially parallel" is "terminology of relative degree, which has no basis of comparison," and therefore "considered broad and relatively unlimited in how it can be interpreted." Moreover, although claims may be given their broadest reasonable interpretation consistent with the specification, the Federal Circuit has repeatedly held that it is improper to interpret a claim limitation so broadly as to effectively remove it from the claim.<sup>14</sup>

<sup>13</sup> Final Office Action at page 3, lines 9-13.

<sup>14</sup> See, e.g., *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 26 USPQ.2d 1018 (Fed. Cir. 1993); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 40 USPQ.2d 1019 (Fed. Cir. 1996) (recognizing that meaning must be given to all words in the claims); *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 249 F.3d 1314, 58 USPQ.2d 1671 (Fed. Cir. 2001); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 72 USPQ.2d 1001 (Fed. Cir. 2004).

Additionally, with respect to the interpretation of relative terminology, the USPTO has stated “[w]hile *generally* and other similar words are sometimes construed liberally to avoid unduly restricting a patent claim, the imprecision of such a term cannot be allowed to negate the meaning of the word it modifies.”<sup>15</sup> Accordingly, in this case, it is improper for the Examiner to construe the term “substantially” so broadly as to read the phrase “parallel to the axis of the vascular prosthesis and the oriented fibrils” out of claim 37, as would be necessary to find that Sato anticipates claim 37.

#### Claims 21, 31, 32 and 34

Similar to independent claim 37, claims 21, 31, 32 and 34 include limitations that recite directions for application of frictional force or rubbing using the term “substantially.” As was the case for independent claim 37, the Examiner’s rejection of claims 21, 31, 32 and 34 is entirely dependent on an unduly broad interpretation of the term “substantially,” which, for the reasons discussed above with respect to claim 37, is legally improper.

#### Claim 16

Claim 16, which depends from claim 11, recites “wherein rubbing [to lift nodes] comprises moving the bristles in the luminal direction.” The Examiner rejected claim 16 under 35 U.S.C. § 102(b) as anticipated by Sato.

As discussed above, Sato is completely silent regarding a direction for the described brushing. Further, a person of ordinary skill would not have considered the Sato method to necessarily involve any of the numerous possible brushing directions, much less the particular direction recited in claim 16. Thus, in accordance with the clear Federal Circuit precedent discussed above, the requirements of claim 16 are not inherent in the Sato disclosure.

In the final Office Action, the Examiner attempted to bolster the argument that rubbing by moving bristles in the luminal direction is inherent in Sato. More particularly, the Examiner argued “any application of a rotary brush along the length of the tubular body inherently is going

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<sup>15</sup> Patent Examination Policy – MPEP Staff, [www.uspto.gov/web/offices/pac/dapp/35usc112.htm](http://www.uspto.gov/web/offices/pac/dapp/35usc112.htm) (further stating as an example that “generally planar” would allow irregular deviations from a perfectly flat surface, but could not broaden the meaning of planar to encompass distinctly arcuate surfaces.)

to pass along the axis.”<sup>16</sup> The Examiner is finding teachings in Sato that simply are not there. For example, the Examiner’s argument is premised on the “fact” that the Sato brush is moved along the length of the Sato tubular body. However, Sato does not teach or suggest that the brush is moved along the length of the tubular body. With respect to the tube of FIG. 4, Sato merely states that that “[t]he nap can be provided on the outer surface of the tube 11, or both the inner and outer surfaces thereof.”<sup>17</sup>

Furthermore, moving the brush along the length of the tubular body is not inherent in the Sato method. In addition to failing to discuss the direction in which the bristles move during rubbing, Sato fails to discuss the relative sizes of tubular body and brush, the extent to which the inner surface of the tubular body would be brushed, or anything else that would suggest that the brush would necessarily be moved in the luminal direction during brushing. Moreover, even if the Sato brush were moved in the luminal direction, such movement would still not necessarily include rubbing by moving bristles in the luminal direction, because it would also be possible to lift the brush off of the luminal surface during movement in that direction.

For at least these further reasons, and in accordance with the clear Federal Circuit precedent discussed above, rubbing to lift nodes by moving bristles in the luminal direction is not inherent in the Sato disclosure.

Sato fails to disclose each and every limitation set forth in a number of Appellant’s claims, including each of independent claims 11, 19, 33 and 37. For at least the reasons discussed above, the Examiner has failed to establish a prima facie case for anticipation of Appellant’s claims 11, 12, 14-17, 19-22, 31-34, and 37-41 under 35 U.S.C. § 102(b). Reversal of this rejection is respectfully requested.

#### **Rejection Under 35 U.S.C. § 102(b) in view of Dzau**

The Examiner rejected claims 19, 23, 24-30, 33, and 34 under 35 U.S.C. § 102(b) as being anticipated by Dzau. Appellant submits that the Examiner’s analysis of the Dzau reference is erroneous, and that Dzau fails to disclose each and every limitation set forth in Appellant’s claims, including each of independent claims 19, 25, and 33.

<sup>16</sup> Final Office Action at page 5, lines 6-8.

<sup>17</sup> Sato at column 4, lines 32-34.

**Independent Claims 19, 25, and 33**

Like Sato, Dzau fails to mention lifting nodes from a luminal surface or any surface of a medical device to create recesses. Unlike Sato, Dzau does not even discuss lifting anything from the luminal surface. Nonetheless, in the final Office Action, the Examiner argued that force of fluid containing cells injected into a lumen of a prosthesis as a sodding medium would inherently cause nodes to be lifted from the luminal surface.<sup>18</sup> More particularly, the Examiner argued that “[i]t is inherent that the force of the fluid causes the nodes to be lifted from the surface since recesses have been formed and the cells adhered and filled them.”<sup>19</sup> Appellant respectfully disagrees with the Examiner’s analysis of Dzau.

Neither the presence of recesses in the Dzau prosthesis, nor the use of a pressure gradient to force the injected fluid through the luminal wall, would necessarily result in, or is even remotely suggestive of lifting nodes above the luminal surface. Consequently, it is not at all clear to Appellant why the Examiner would cite these features of Dzau as supporting a conclusion that injecting a sodding medium as taught by Dzau necessarily results in lifting nodes above the Dzau prosthesis surface. The Examiner is again relying on an improper finding of an inherent disclosure.

Stated another way, Appellant respectfully suggests that the teachings of Dzau would not have even suggested to a person of ordinary skill in the art that lifting nodes from the luminal surface was a possible result of the injection of fluid, at least not without the benefit of hindsight and Appellant’s disclosure. The teachings of Dzau certainly would not have led such a person to conclude that nodes were certainly or necessarily lifted from the Dzau luminal surface to create recesses when a sodding medium was injected into the Dzau prosthesis lumen.

Furthermore, contrary to the requirements of claims 19 and 25, the recesses formed in the Dzau prosthesis are formed by stretching, prior to injection of the sodding medium. Thus, even if the injection of a sodding medium as taught by Dzau resulted in the application of some force to the luminal surface of the Dzau prosthesis, it would not define a plurality of recesses, as required by claims 19 and 25. In other words, Dzau is clear that the only recesses on the Dzau device are defined by stretching, which occurs prior to injection of fluid, and are not defined by

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<sup>18</sup> Final Office Action at page 3, lines 20-23.

<sup>19</sup> *Id.*

the injection of the fluid.<sup>20</sup> The Examiner apparently recognized this difference between the teachings of Dzau and the requirements of claim 19 and 25, when the Examiner stated "it is inherent that the force of fluid causes the nodes to be lifted from the surface since recesses have been formed...."<sup>21</sup>

For at least the reasons discussed above, the Examiner failed to establish a prima facie case of anticipation of claims 19, 23, 24-30, 33, and 34 by Dzau. Accordingly, the rejection Appellant's claims 19, 23, 24-30, 33, and 34 based on Dzau should be reversed.

#### **Rejection Under 35 U.S.C. § 103(a) in view of Sato**

The Examiner rejected claims 18 and 38 as being obvious under 35 U.S.C. § 103(a) in view of Sato. Appellant respectfully disagrees with the Examiner's conclusion regarding obviousness of claims 18 and 38. Sato fails to disclose or suggest the inventions defined by Appellant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 18 and 38 both require that the luminal surface of the vascular prosthesis is the outer surface when the prosthesis is rubbed to lift nodes from the surface. Claims 18 and 38 both further require that the prosthesis is everted after rubbing.

Initially, Appellant notes that each of claims 18 and 38 depends from one of independent claims 11 and 37, and is patentable over Sato for at least the reasons discussed above with respect to those independent claims. Further, the Examiner's arguments in support of a prima facie case of obviousness for these claims lack evidentiary support and are legally improper.

In rejecting claims 18 and 38, the Examiner acknowledged that Sato fails to disclose or suggest these limitations of claims 18 and 38, but argued that it would have been an obvious matter of "design choice" to modify the Sato method to rub the Sato prosthesis with the luminal surface as the outer surface and then evert the prosthesis, "since applicant has not disclosed that using an everted prosthesis provides any advantage, or solves a stated problem, or is used for any particular purpose."<sup>22</sup>

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<sup>20</sup> Dzau, column 5, lines 13-18.

<sup>21</sup> Final Office Action at page 3, lines 20-23 (emphasis added).

<sup>22</sup> Final Office Action mailed December 22, 2006 at page 4.

The Examiner, however, is relying on impermissible conclusory statements of obviousness to support the rejection of claims 18 and 38. Unsupported assertions of “design choice” are contrary to clear Federal Circuit precedent, which holds that a finding of obviousness must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.<sup>23</sup> As the Supreme Court recently reiterated, to establish obviousness, the Examiner must identify an apparent reason why one of ordinary skill in the art would have been motivated to make a modification or combination to arrive at the claimed invention.<sup>24</sup> Thus, the Examiner’s reasoning that claims 18 and 38 are obvious because Appellant has not “disclosed that using an everted prosthesis provides any advantage, or solves a stated problem, or is used for a particular purpose,” is legally improper.

Whether Appellants’ claims are obvious depends upon what is taught in the prior art, rather than Appellant’s disclosure<sup>25</sup>. Consequently, because the Examiner has failed to establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill to modify the Sato method to include brushing and then everting a prosthesis, the rejection of claims 18 and 38 should be reversed.

Moreover, the Examiner’s characterization of Appellant’s disclosure is incorrect. For example, at paragraph [0061], the disclosure states:

It is believed to be possible to rub a luminal surface without everting the prosthesis, e.g., by running a brush through the lumen one or more times. Accordingly, everting the prosthesis for processing is not essential to the invention. Even so, mounting the prosthesis on a supporting mandrel, as shown in FIG. 2, may allow for very precise control of the rubbing.

Further, paragraph [0063] describes an example in which “[t]he prosthesis had been everted so that that luminal surface was more accessible.”

In further support of the rejection of claims 18 and 38, the Examiner concluded that “[o]ne of ordinary skill in the art . . . would have expected Applicant’s invention to perform equally well with the rubbed prosthesis taught by Sato or the claimed everted prosthesis in claim(s) 18,38 because both prostheses perform the same function of providing recesses for cell ingrowth.”<sup>26</sup> Regardless of whether Appellant’s method of claims 18 and 38 and the method

<sup>23</sup> *In re Lee*, 277 F.3d 1338, 61 USPQ.2d 1430 (Fed. Cir. 2002) (emphasis added).

<sup>24</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 167 L. Ed. 2d 705, 722, No. 04-1350, Slip op. at 14 (Apr. 30, 2007).

<sup>25</sup> *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ.2d 1443, 1445 (Fed. Cir. 1992).

<sup>26</sup> Final Office Action at page 4, lines 14-18.



taught by Sato result in a prosthesis that achieves the same function, the Examiner has not provided a reason why one of ordinary skill in the art would have been motivated to modify the Sato method to include the limitations of claims 18 and 38.

Consistent with the Federal Circuit precedents discussed above, the Supreme Court has stated that there must be "some rationale, articulation, or reasoned basis" to support the legal conclusion of obviousness.<sup>27</sup> The reason for modification need not conform to the particular motivation or objective of the patent applicant.<sup>28</sup> However, there still must be some need or problem known in the art that would provide a reason for combining elements in the manner claimed.<sup>29</sup> The Examiner has failed to provide a reason for modification other than "design choice."

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Appellant's claims 18 and 38 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

### SUMMARY

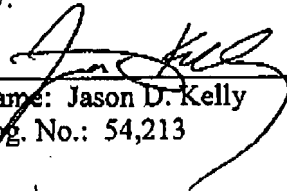
The Examiner has failed to meet the burden of establishing a prima facie case of anticipation or obviousness with respect to claims 11, 12, 14-34, and 37-41. In view of the Appellant's arguments, the final rejection of claims 11, 12, 14-34, and 37-41 is improper and should be reversed, and all of the pending claims should be allowed.

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5-21-07

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<sup>27</sup> *Alza Corp. v. Mylan Labs.*, 464 F.3d 1286, 1290, 80 USPQ.2d 1001, 1005 (Fed. Cir. 2006) (citing *In re Kahn*, 441 F.3d 977, 987, 78 USPQ.2d 1329 (Fed. Cir. 2006)).

<sup>28</sup> *KSR*, Slip op. at 16.

<sup>29</sup> *Id.*

**APPENDIX A**  
**THE CLAIMS ON APPEAL**

Claims 1-10 (Canceled).

Claim 11 (Previously Presented): A method comprising rubbing a luminal surface of a vascular prosthesis with a tool to lift nodes from the luminal surface to define a plurality of recesses.

Claim 12 (Original): The method of claim 11, wherein the vascular prosthesis comprises expanded polytetrafluoroethylene.

Claim 13 (Canceled).

Claim 14 (Original): The method of claim 11, wherein the tool comprises a wheel brush comprising bristles.

Claim 15 (Original): The method of claim 14, wherein the brush comprises bristles of at least one of metal and nylon.

Claim 16 (Previously Presented): The method of claim 14,  
wherein the vascular prosthesis has a generally tube-shaped structure having an axis,  
wherein the luminal surface defines a luminal direction along the axis, and  
wherein rubbing comprises moving the bristles in the luminal direction to cause the bristles to come in contact with the luminal surface.

Claim 17 (Original): The method of claim 11, further comprising mounting the prosthesis on a mandrel.

Claim 18 (Original): The method of claim 11, wherein the luminal surface is an outer surface of the vascular prosthesis when the vascular prosthesis is rubbed with the tool, the method further comprising everting the vascular prosthesis after rubbing.

Claim 19 (Previously Presented): A method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses.

Claim 20 (Original): The method of claim 19, wherein applying the force comprises rubbing the surface with a tool.

Claim 21 (Previously Presented): The method of claim 20, further comprising rubbing the surface with the tool in a direction that is substantially perpendicular to an orientation of the nodes.

Claim 22 (Original): The method of claim 20, wherein the tool comprises a wheel brush comprising bristles.

Claim 23 (Original): The method of claim 19, wherein applying the force comprises applying a pressurized fluid to the surface.

Claim 24 (Original): The method of claim 23, wherein the fluid comprises one of water and air.

Claim 25 (Previously Presented): A method comprising:

applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface comprising nodes formed of polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses; and seeding cells on the surface.

Claim 26 (Original): The method of claim 25, further comprising harvesting the cells.

Claim 27 (Original): The method of claim 26, wherein the seeding is performed less than fifteen minutes after the harvesting.

Claim 28 (Original): The method of claim 25, wherein the medical device comprises a vascular prosthesis.

Claim 29 (Original): The method of claim 28, wherein the cells comprise endothelial cells.

Claim 30 (Original): The method of claim 29, wherein the endothelial cells comprise endothelial precursor cells.

Claim 31 (Previously Presented): The method of claim 11, wherein the luminal surface comprises fibrils oriented to interconnect the nodes, and rubbing comprises rubbing the luminal surface in a direction substantially parallel to the oriented fibrils.

Claim 32 (Previously Presented): The method of claim 19, wherein the surface comprises fibrils oriented to interconnect the nodes, and the force is applied to the surface in a direction substantially parallel to the oriented fibrils.

Claim 33 (Previously Presented): A method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, the luminal surface comprising nodes and fibrils, the method comprising applying a frictional force to the luminal surface to lift at least some of the nodes from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils.

Claim 34 (Previously Presented): The method of claim 33,  
wherein the vascular prosthesis has a generally tube-shaped structure having an axis,  
wherein the fibrils are oriented to interconnect the nodes, and  
wherein applying a frictional force to the luminal surface comprises applying the frictional force in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils.

Claims 35 and 36 (Canceled).

Claim 37 (Previously Presented): A method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, wherein the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and wherein the vascular prosthesis has a generally tube-shaped structure having an axis, the method comprising rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses.

Claim 38 (Previously Presented): The method of claim 37, wherein the luminal surface is an outer surface of the vascular prosthesis when the vascular prosthesis is rubbed with the brush, the method further comprising everting the vascular prosthesis after rubbing.

**Claim 39 (Previously Presented):** The method of claim 37, wherein rubbing the luminal surface with a brush comprises contacting the luminal surface with the brush from within the tube-shaped structure of the vascular prosthesis.

**Claim 40 (Previously Presented):** The method of claim 39, wherein rubbing the luminal surface with a brush comprises moving the brush through the tube shaped structure in a direction substantially parallel to the axis of the vascular prosthesis.

**Claim 41 (Previously Presented):** The method of claim 37, wherein the vascular prosthesis comprises an abluminal surface, and wherein the abluminal surface comprises nodes and fibrils oriented to interconnect the nodes, the method further comprising rubbing the abluminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses

**APPENDIX B**

**EVIDENCE**

None.

**APPENDIX C**  
**RELATED PROCEEDINGS**

None.